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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,936	12/14/2005	Martina Kuhn	B1180/20039	2983
3000 7590 04/11/2008 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOV, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212			EXAMINER NAFF, DAVID M	
			ART UNIT 1657	PAPER NUMBER
			NOTIFICATION DATE 04/11/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/540,936	Applicant(s) KUHN ET AL.	
	Examiner David M. Naff	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/25/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A preliminary amendment of 7/15/05 amended the specification and claims 1-12 and 14-22, and added new claims 23-26.

Claims examined on the merits are 1-26, which are all claims in
5 the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.
112:

10 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph,
as being indefinite for failing to particularly point out and
15 distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 3, "biological material" is uncertain as to meaning and scope. Material that is biological and not biological is relative and subjective and would be uncertain.

20 In line 4 of claim 1, "nanoparticulate reinforcing material" is unclear how "reinforcing" defines the material since the material that is reinforced and the result that is being reinforced is not specified. The difference in nanoparticulate material that is reinforcing and not reinforcing would be relative and subjective and
25 uncertain.

Bridging the last two lines, claim 1 is unclear what links the nanoparticles together, and when the nanoparticles are linked, i.e.

before being embedded in the ceramic substrate or after being embedded.

In the last line, claim 1 is unclear as to when the nanoparticles are formed from a nanoparticulate sol, i.e. before or after the nanoparticles are embedded in the substrate, and it is uncertain as to steps involved in forming the nanoparticles from the sol. When process limitations are required, clear, distinct and positive process steps should be set forth. The claim is unclear as to what cross-links the substrate material in the last line. The claim is unclear as to the functional relationship of the nanoparticles being linked to being formed from the sol and to the cross-links of the substrate.

Bridging the last two lines, claims 3 is unclear as to material that would be hydrolysis products of trialkoxy silanes since steps of hydrolysis have not been required. Reciting "mixtures thereof" in the last line is confusing since different materials that can be mixed have not been specified. Reciting "trialkoxo silanes" in the plural does not set forth different materials.

In line 2 of claim 4 and where recited in any other claim, "a proportion of" is unclear as to whether this is a proportion of the percent subsequently required. It is suggested "a proportion of" be deleted.

In claim 6, "cell groups" and "biologically effective macromolecules" are uncertain as to meaning and scope and materials that are within and not within the scope of these terms.

In line 2 of claim 7, the difference in "living" and "viable" is uncertain. The difference in an organism that is living and not viable or the converse is uncertain.

In the last line of claim 9, "animal cell groups" and "vegetable
5 cell groups" are uncertain as to meaning and scope. How "groups" define the animal or vegetable cell is unclear. The difference in an animal cell and a vegetable cell when a group and not a group is uncertain.

In line 2 of claim 9, "a proportion of" should be deleted, and
10 "a" before "dry" should be changed to --- the --- to be clear. This type of amendment applies also to claim 14.

Claim 11 is unclear as to an additive that increases biological activity since a material that has biological activity has not been previously required.

15 Method claim 15 is unclear by failing to set forth clear, distinct and positive steps, and not providing a clear functional relationship between the different steps so that it is clear how each step functions in forming the composite in relation to all other steps, and each step has clear antecedent basis in a previous step.
20 The claim is unclear in lines 7-9 as to the meaning and scope of "reinforcing the ceramic composite material by neutralization of the slurry with the at least one nanoparticulate reinforcing material". Physical phenomena that constitute "reinforcing" is uncertain since the function and result of reinforcing has not been set forth. How

can the nanoparticulate neutralize since neutralization normally results from changing pH?

In the last line, claim 14 is unclear as to steps that constitute a "freezing process", and how the freezing process forms the composite
5 material. The material that is subjected to freezing, and the steps used for freezing is unclear.

Claim 14 is unclear when in the process the nanoparticulate required in claim 1 is formed.

Claim 17 is unclear by requiring "additional additives" (bridging
10 lines 1 and 2) since a previous additive has not been required.

Claim 18 is unclear as to structure that would be a mold since the function of the mold has not been specified.

Claim 21 in line 4 is unclear as to how the biocatalyst and biofilter differ from the ceramic composite material since structure
15 of the biocatalyst and biofilter has not been required that is different from the ceramic composite material structure.

Claim 22 is unclear how the ceramic materials produced differ from the ceramic composite material since the ceramic materials have not been required to have features that would distinguish them from
20 the ceramic composite material. Furthermore, the method of producing the ceramic materials is unclear how the method produces the ceramic materials since the only step required is providing the ceramic composite material. This single step will not produce ceramic materials different from the ceramic composite material.

In claim 23, "composite material is a molding" is unclear how "molding" defines the composite material since the function of molding is not set forth. This also applies to "A molding" in claim 24.

Claim 25 is unclear as to process steps that constitute a
5 freezing process.

Claim 26 is unclear as to the meaning of "neutralization of the slurry with the inorganic nanosol" since it is unclear how the nanosol functions to neutralize when neutralization is given its normal and art recognized meaning. Neutralization normally involves changing the
10 pH of a material to a neutral pH.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the
20 invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly
25 owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35

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U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuehn et al (DE 10065138) in view of Trieu et al
5 (20020115742) and Bottcher et al (DE 19929616) and Wei et al (6,696,258).

The claims are drawn to a ceramic composite material comprising a ceramic substrate having homogenously embedded a biological material and a nanoparticulate reinforcing material. Also claimed is a method
10 of making the composite by producing a slurry of the substrate and a dispersion of the biological material, adding to the slurry an inorganic nanosol capable of gelling, and carrying out neutralization or a freezing process to form the composite.

According to the present specification (paragraphs bridging pages
15 2 and 3 and pages 4 and 5), the present invention is a modification of ceramic moldings of DE 10065138 (Kuehn et al) by providing in the ceramic a nanoparticulate reinforcing material and biological material.

Trieu et al disclose bioactive nanocomposites containing a
20 homogeneous mixture of a biocompatible polymer and a bioactive particulate ceramic (paragraph 0009). Pharmacological agents can also be present (paragraph 0037). The particulate ceramic is in the form of nanoparticles (paragraphs 0053, 0054 and 0056), and reinforces the polymer (paragraph 0047, line 5 from the last line of the paragraph).

Bottcher et al disclose a coating agent for protecting ceramics or glass against oxidation comprising a phosphorous silicate nansol formed by hydrolysis of metal alkoxides or metal halides and an acidic organophosphate solution (For example, see the title and abstract and
5 page 3).

Wei et al disclose forming a sol-gel matrix mesoporous material (col 9, lines 25-53 and col 13, lines 47 to col 14, line 2). A base catalysis used in hydrolysis to produce the matrix can be a Group IA and Group IIA metal alkoxide (col 9, line 41). When a biologically
10 active agent is provided in the matrix, neutralizing is carried out after hydrolysis before adding the biologically active agent (col 9, lines 54-67). The biologically active agent can be a microorganism (col 14, line 5).

When producing the ceramic moldings of Kuehn et al, it would have
15 been obvious to provide ceramic nanoparticles in the moldings to provide reinforcement as suggested by Trieu et al providing ceramic nanoparticles in a polymer to reinforce the polymer. It would have been obvious to add the nanoparticles as a nanosol as suggested by Bottcher et al coating ceramics with a nanosol. The nanosol will
20 obviously contain nanoparticles. Providing microorganisms as a biologically active agent to obtain the expected function of the microorganisms in the ceramic moldings of Kuehn et al would have been suggested by Wei et al providing microorganisms in sol-gel matrix since the ceramic molding of Kuehn et al is formed by a sol-gel
25 process. When adding microorganisms, it would have been obvious to

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neutralize acid or base before adding the microorganisms as suggested by Wei et al.

Conclusion

Any inquiry concerning this communication or earlier
5 communications from the examiner should be directed to David M. Naff
whose telephone number is 571-272-0920. The examiner can normally be
reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,
the examiner's supervisor, Jon Weber can be reached on 571-272-0925.
10 The fax phone number for the organization where this application or
proceeding is assigned is 571-273-8300.

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10 Service Representative or access to the automated information system,
call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit
1657

DMN
15 3/31/08